IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SIEMENS MEDICAL SOLUTIONS USA, INC.,	
Plaintiff/ Counterclaim-Defendant,	C.A. No. 07-190-SLR
v.	JURY TRIAL DEMANDED
SAINT-GOBAIN CERAMICS & PLASTICS, INC.,	**REDACTED - PUBLIC VERSION**
Defendant/Counterclaim-Plaintiff.	

DEFENDANT'S *CORRECTED* BRIEF IN OPPOSITION TO PLAINTIFF'S APPLICATION FOR A PRELIMINARY INJUNCTION

Jesse A. Finkelstein (#1090)
Finkelstein@rlf.com
Jeffrey L. Moyer (#3309)
Moyer@rlf.com
Kelly E. Farnan (#4395)
Farnan@rlf.com
Richards, Layton & Finger, P.A.
One Rodney Square, P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
Attorneys for Defendant/ Counterclaim-Plaintiff Saint-Gobain Ceramics & Plastics, Inc.

OF COUNSEL:

Frederick L. Whitmer
John C. Ohman
Thelen Reid Brown Raysman & Steiner LLP
875 Third Avenue
New York, NY 10022
(212) 603-2000

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INTRODUCTION AND SUMMARY OF ARGUMENT

Saint-Gobain Ceramics and Plastics, Inc. ("Saint-Gobain") submits this answering brief, together with the Declarations of Drs. Michael Mayhugh and Kenneth McClellan, to demonstrate that Plaintiff Siemens Medical Solutions USA, Inc. ("Siemens") does not deserve the extraordinary remedy of a preliminary injunction against Saint-Gobain for the alleged infringement of United States Patent No. 4,958,080 ("the '080 Patent").

Despite the aggressive rhetoric of Siemens' Opening Brief in Support of its Motion for Preliminary Injunction, ("Siemens Brief") the facts underlying this action demonstrate that Saint-Gobain has neither "[attempted] to gain the benefit of the '080 patent technology without taking a patent license," nor "[substituted] only a small amount of the lutetium in the LSO crystals claimed in the '080 Patent with a dash of another rare earth element (yttrium)." See Siemens Brief at 1. First, Saint-Gobain *has* taken a license on another United States Patent, U.S. Patent No. 6,624,420 ("the '420 Patent"), which claims, *inter alia*: "A scintillator detector for high energy radiation comprising: a monocrystalline structure of cerium doped lutetium yttrium orthosilicate..." with specific ranges of lutetium and yttrium.

Thus, the compound that Siemens now argues is "equivalent" to the LSO crystal, claimed in the '080 Patent, is itself protected by a later patent, issued by the United States Patent and Trademark Office ("the USPTO"), which was allowed over the '080 Patent as a reference. The fact that the USPTO granted the '420 Patent even in the face of the '080 Patent is signal evidence that the USPTO considered the LYSO crystal both non-obvious and inventive. As the Federal Circuit has held only recently, "We have not directly decided whether a device---novel and separately patentable because of the incorporation of an equivalent feature---may be captured by the doctrine of equivalents, although we have held that when a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, is at least considerably more difficult to make out. But there is a strong argument that an equivalent cannot be both non-obvious

and insubstantial." *Festo Corp. v Shoketusu Kinzoku Kogyo Dabushiki Co. Ltd.*, 493 F.3d 1368, 1380 (Fed. Cir., July 5, 2007)(footnotes omitted). The logic of that holding is unmistakable. The issuance of a later patent on a device or compound that is later accused of infringement is highly relevant to an issue of equivalence, for "the PTO must have considered the accused product to be nonobvious with respect to the [previously] patented composition." *Hoganas AB v. Dresser Industries, Inc.* 9 F.3d 948 954 (Fed. Cir. 1993).

Siemens' dismissive description of the amount of yttrium found in Saint-Gobain's LYSO crystal as "a dash", inappropriately characterizes the substitution of yttrium for certain lutetium atoms in Saint-Gobain's patented LYSO crystal as "insubstantial."[1] But, as Judge Nies of the Federal Circuit has observed, "A substitution in a patented invention cannot be both nonobvious and insubstantial." *See Roton Barrier, Inc. v Stanley Works,* 79 F.3d 1112, 1128 (Fed. Cir. 1996)(Nies, J., additional views). The logical conclusion of Siemens' argument here then, on this application for a preliminary injunction, is that the USPTO erred in granting the '420 Patent.[2] As Saint-Gobain elaborates within, the presumption of validity that attaches to the '420 Patent makes the grant of Siemens' motion for a *preliminary* injunction unjustified, for the grant of the preliminary injunction would effectively be a judgment, at a preliminary stage of this proceeding, that the '420 Patent is invalid. And, given the fact that the '080 Patent expires in October 2008, Siemens' requested *preliminary* injunction will be the only injunction: as if the end of a *permanent* injunction.

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[1] Indeed, Siemens' expert, Dr. Weber, asserted in his deposition that in certain circumstances even 5 parts per million might have material consequences. Weber Dep. Trans. at 30:23-33:22. Under this calculus, the Saint-Gobain LYSO crystal represents the incorporation of 100,000 parts per million; hardly the "dash" Siemens would characterize it to be.

[2] In fact, as the McClellan Declaration explains, the USPTO granted McClellan a patent on a LYSO crystal for scintillation purposes, the 6,323,489 Patent ("the '489 Patent), which was subsequently cancelled only as a result of an interference proceeding between the application for what became the '420 Patent and the '489 Patent. Thus, not once, but twice did the Patent Office consider the patentability of the LYSO crystal as a scintillator, ultimately concluding that Chai, not McClellan, deserved the award of a patent.

Saint-Gobain, however, does not rely exclusively on the existence of the '420 Patent (and its legal consequences) to defeat Siemens' effort to extend whatever rights it has to enforce the '080 Patent beyond their lawful limit. As the Declaration of Dr. Kenneth McClellan elaborates, the incorporation of yttrium into the crystalline structure of an LSO crystal expands the matrix of the lattice structure of the crystal beyond the dimensions of an LSO crystal, which can therefore accommodate a higher concentration of the doping agent, cerium. That characteristic lets the LYSO crystal have fewer opportunities for the light emitted from the crystal to be "trapped" within the crystal as a result of ricocheting inside the crystal until the light finds a "hole" in the lattice structure.[3] This improves the passage of light through the crystal. Dr. McClellan also explains in greater detail in his Declaration that alloying LSO with YSO yields the LYSO crystal that possesses many significant and desirable advantages, including a reduced melting point for the manufacture of the crystal, less propensity for formation of inclusions, which would "trap" light and therefore compromise performance of the crystal as an effective scintillator, and easier incorporation of cerium into the host lattice, thereby increasing the overall effectiveness of the crystal as a scintillator.

All these reasons undermine Siemens' ability to argue credibly that the LYSO crystal is an "equivalent" to the LSO crystal as a mere "insubstantial" change over the LSO crystal. The USPTO did not regard the change as "insubstantial;" and that after the prosecution of not one, but two separate applications. It remained of that view after the interference proceeding, from which the '420 Patent emerged as a valid exercise of the USPTO's charge to examine applications and grant patents to deserving applicants.

Indeed, there is a substantial question whether Siemens is entitled to *any* range of equivalents for the '080 Patent. The reason is straightforward. The law limits the ability of a patentee to have the benefit of a range of equivalents if, during prosecution, claims were amended to narrow the literal scope

[3] In less technical jargon, the expansion of the lattice by the addition of the yttrium creates bigger "holes" through which the emitted light can escape.

of a claim for reasons of patentability. *Festo Corp. v. Shoketusu Kinzoku Kogyo Dabushiki Co. Ltd.*, 344 F.3d 1359, 1367 (Fed.Cir. 2003)(en banc). During the prosecution of the parent application to the '080 Patent, Claim 1 was amended in two ways.[4] First, it was amended to add the term "transparent" as a modifier to scintillator, thereby narrowing the claim from all scintillators to only *transparent* scintillators. Next, the concentration of cerium was now claimed to be that which exists in a single crystal instead of the concentration of cerium in the "melt" from which the crystal was pulled. This change, as we describe more fully within, had the effect of excluding certain crystals from infringement *after* the amendment that fell within the scope of the unamended claim. Both of these changes were clearly related to the patentability of the application.

The amendment to include "transparent" was in response to an obviousness rejection. The amendment respecting the concentration of cerium was made in response to an indefiniteness rejection. Thus, this amendment was likewise directed at the patentability of the claim.

Under current law, these facts create a presumption that the patentee is not entitled to a range of equivalents within the surrendered territory of the amendments. *Festo Corp. v. Shoketusu Kinzoku Kogyo Dabushiki Co. Ltd.*, 344 F.3d 1359, 1367 (Fed.Cir. 2003)(en banc). A patentee may, however, rebut that presumption by showing either that the alleged equivalent was "unforeseeable" at the time of the narrowing amendment or that the rationale for the narrowing amendment had only a tangential relationship to the subject equivalent. Finally, a patentee has the opportunity to offer "some other" presumably compelling reason to show that the patentee could not reasonably have been expected to have described the alleged equivalent. Siemens cannot meet that standard. Once again, the reasons are straightforward and indisputable.

[4] It is beyond doubt that amendments to parent applications have the effect of restricting the scope of later patents that rely on the earlier application. *See, e.g., Jonsson v. The Stanley Works*, 903 F.2d 812 (Fed. Cir. 1990).

YSO was known as a scintillator at the time of the '080 prosecution. The USPTO's initial rejection of the '420 application in light of the '080 Patent similarly reflects the USPTO's view that, at the time of the application for the '080, the inclusion of yttrium was forseeable. The demonstrably superior performance that the LYSO crystal showed the USPTO, however, prevailed to persuade the USPTO that the inclusion of yttrium was not an insubstantial change, but a novel and non-obvious, true invention, separately worthy of a patent. These facts doom Siemens' endeavor to rebut the presumption the law imposes on Siemens (who stands in the shoes of the applicant for the '420 Patent) for the narrowing amendments that the applicant advanced for the purpose of ultimately obtaining his patent. Siemens accordingly is not entitled to recapture ground lost during prosecution for the purpose of obtaining the patent in the first place by advancing an argument now that a LYSO crystal is "equivalent" to the LSO crystal claimed in the '080 Patent.[5]

So Siemens fails on the most fundamental fulcrum of an application for preliminary injunctive relief, a strong showing of a likelihood of success on the merits. *See Digene Corporation v. Ventana Medical Systems, Inc,* 2007 WL 1364401 (D. Del. 2007). The existence of the presumptively valid '420 Patent, buttressed by the advantages and benefits that the LYSO crystal offers over the LSO crystal as McClellan describes and the at-least-doubtful scope of any range of equivalents to which Siemens might be entitled, casts a deep pall of doubt over the vitality of Siemens' application. Though this is reason alone to deny the application for preliminary injunction, there is still more.

The Declarations of Drs. McClellan and Mayhugh demonstrate that the LYSO compound offers significant and scientifically demonstrable advantages over the LSO crystal for scintillation properties. In addition, Dr. Mayhugh's Declaration makes it clear that Saint-Gobain acted reasonably and responsibly in connection with its activity to develop and manufacture a commercially feasible LYSO crystal. **REDACTED**

[5] Siemens' position misapprehends the reality of the chemical properties of these elements---or is blind to them to serve its litigation strategy.

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Saint-Gobain had initially negotiated with the Regents of the University of California, the assignee of McClellan's '489 Patent, to obtain rights to the patented LYSO crystal; but Saint-Gobain eventually concluded a license with the University of Central Florida, the assignee of Chai's '420 Patent, which had secured, ultimately, the patent rights to the LYSO crystal following the interference proceedings in the USPTO between McClellan and Chai. Then, when Siemens suggested that the soon-to-expire '080 Patent covered the LYSO crystal, a conclusion that Saint-Gobain never anticipated or understood, Saint-Gobain retained the law firm of Foley & Lardner, which rendered an extensive opinion, concluding, correctly, that Siemens could not sustain a claim of infringement against Saint-Gobain.

Finally, the remaining equitable factors, relevant to the grant or denial of a preliminary injunction, all favor Saint-Gobain. Principally, the balance of equities and harm strongly favors Saint-Gobain.

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In case after case, the Courts of this District have declined to enter preliminary injunctions in analogous circumstances. *See, Cordis Corp v. Boston Scientific Corp.*, 2003 WL 22843072 (D. Del. 2003); *Novozymes A/S v. Genencor International, Inc.*, 2005 WL 2716496 (D.Del 2005); *Digene Corporation v. Ventan Medical Systems, Inc.*, 2007 WL 1364401 (D.Del 2007).

The conclusion that the preliminary injunction should be denied is further supported by the fact that there is at least one other supplier of the LYSO crystal in the marketplace, known to Siemens from the public literature, and as conceded by Dr. Weber, Siemens' expert in this case. An injunction against Saint-Gobain would accordingly inflict harm on Saint-Gobain by denying it the ability to fulfill its contractual arrangements but *not* prevent from obtaining the LYSO crystal elsewhere to continue its commercial activity in competition with Siemens. Having chosen to spend its resources to pursue

Saint-Gobain, only a supplier of the LYSO crystal, and not Siemens' direct competitor, Siemens must accept the consequence that even success on this motion does not secure what is Siemens' self-proclaimed goal, the staunching of competition from

Finally, given that in less than one year the '080 Patent will expire, where Saint-Gobain has been supplying the LYSO crystal for less than two full years, there is a notable lack of credible evidence that Siemens is or will suffer "irreparable" harm, that is, harm not compensable in money damages, were the preliminary injunction denied.[6] Saint-Gobain is a substantial company; the sales of allegedly infringing PET Scanners, utilizing Saint-Gobain's LYSO crystal, were limited and have a terminal date of October 6, 2008, when the '080 Patent, whatever its exclusionary reach may have been, will pass into the public domain of knowledge.

The litany of the substantial reasons for the denial of Siemens' ill-conceived preliminary injunction motion, which has had the effect of burdening Saint-Gobain and the Court with an expedited, and necessarily truncated review of some of the merits of this action, is long and meritorious. Siemens has failed to demonstrate with the requisite, substantial clarity that it has satisfied the exacting standard to secure the extraordinary remedy of a preliminary injunction against Saint-Gobain on this motion.

[6] Siemens' suggestion that its self-described erosion of market share is due to the alleged infringement, though more appropriately addressed as a damage question at a later point, nevertheless deserves passing refutation. General Electric is another competitor in the marketplace for PET Scanners. The equation that Siemens asks this Court to accept, that a preliminary injunction against Saint-Gobain would translate into the elimination of the "reason" Siemens' market share has declined, is unsustainable. It goes beyond the needs of this motion to analyze this reality more deeply than this: there are demonstrable and significant factors in the marketplace, namely a robust and capable competitor of Siemens that affects Siemens' ability to compete.

STATEMENT OF FACTS[7]

Defendant Saint-Gobain is a United States subsidiary of the storied French concern, Compagnie de Saint-Gobain S.A. ("Saint-Gobain (France)"), which was originally created by Jean-Baptiste Colbert under the name Compagnie du Noyer in 1665 during the reign of King Louis XIV. One of its earliest projects was to build the Hall of Mirrors at the Château de Versailles outside Paris. During the ensuing centuries Saint-Gobain (France) has grown both in its geographic reach and the diverse range of its business activities. Operating in 54 countries and employing a workforce of over 207,000 people, Saint-Gobain (France) -- together with its affiliates and subsidiaries, including the named Defendant in this action -- is today either the European or global leader in each of its many businesses, focused in five sectors: construction products, high-performance materials, packaging, flat glass and building distribution.

It is the high-performance materials sector of Saint-Gobain's business that is implicated in this dispute. Mayhugh Decl. ¶ 5. Saint-Gobain is a worldwide leader in the manufacture and development of engineered materials such as abrasives, ceramics and plastics, reinforcements and composites, textile solutions, grains and powders and crystals. Mayhugh Decl. ¶ 5.

1. Saint-Gobain's LYSO Product and This Dispute.

Of the many materials Saint-Gobain produces, processes and distributes to its customers in the medical and healthcare industry, one of particular note is a cerium-doped lutetium yttrium orthosilicate ("LYSO") crystal that serves a critical function in certain highly sophisticated positron emission tomography ("PET") scanners manufactured by **REDACTED** Mayhugh Decl. ¶ 6. These PET scanners, described more fully below, are used to assist the medical community to detect and diagnose cancers as well as other diseases and organic conditions inside the

[7] This Statement of Facts is derived largely from the Declarations of Dr. Michael Mayhugh and Dr. Kenneth McClennan, submitted simultaneously herewith. References to these Declarations shall be in the format: Mayhugh Decl. ¶___ and McClellan Decl. ¶___.

bodies of human (and non-human) patients in hospitals and clinics throughout the world. Mayhugh Decl. ¶ 6. Saint-Gobain manufactures the LYSO crystals it sells to under a patent license that Saint-Gobain negotiated and executed with the University of Southern Florida, assignee of U.S. Patent No. 6,624,420 to Chai. Mayhugh Decl. ¶ 6.

Siemens Medical's allegations of infringement are without merit. Mayhugh Decl. ¶ 6. Saint-Gobain neither copied the cerium-doped lutetium orthosilicate ("LSO") scintillator crystals nor avoided a patent license. Mayhugh Decl. ¶ 21. Saint-Gobain's manufacture and sale of the patented LYSO crystal is authorized by the assignee of the '420 Patent. Mayhugh Decl. ¶ 16.

2. Saint-Gobain Becomes a Supplier of Materials Used in PET Scanners.

Since at least the 1970's, Saint-Gobain and its predecessors, Bicron, Harshaw and Crismatec, have been involved in transforming raw materials into advanced materials used in PET detectors and scanners. Mayhugh Decl. ¶ 7. PET is a highly advanced, specialized medical imaging technology that uses short-lived radioactive substances to produce three-dimensional colored images of those substances functioning within the body. Mayhugh Decl. ¶ 7. These images are capable of providing the medical community with functional images containing information not available through more conventional x-ray, MRI (magnetic resonance imaging) and other, older scanning technologies. Mayhugh Decl. ¶ 7. A critical component of a PET scanner is a "detector" comprised of a scintillator crystal that converts particular kinds of radiation into photons and an attached device that converts those photon light pulses into electrical signals. Mayhugh Decl. ¶ 7.

For many years, however, PET remained largely a medical research and "R&D" hospital activity, limited by perceived clinical utility. Mayhugh Decl. ¶ 8. This circumstance constrained the commercial market for PET detectors. Mayhugh Decl. ¶ 8.

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described more fully below, the development and manufacture of commercially usable and robust scintillation crystals is a matter of some considerable skill and experience, requiring a substantial amount of capital and research expertise. Mayhugh Decl. ¶ 8. At the time, the required effort was not justified.

3. **SPECT Transforms the PET Scanner Market.**

In the late 1990s, however, the market had changed. The advent of dual head PET/single photon emission computed tomography ("SPECT"), a nuclear medicine procedure in which a "gamma camera" rotates around a patient and takes pictures from many angles, from which a computer forms a tomographic (cross-sectional) image and the upswing in the manufacture of dedicated "full ring" PET machines opened up entirely new commercially attractive approaches for the use of PET scanning and their attendant medical benefits. Mayhugh Decl. ¶ 9.

As the decade progressed, Saint-Gobain provided thick curved NaI(Tl) plates **REDACTED** for PET. Mayhugh Decl. ¶ 9. The dual head PET/SPECT application was further served by a variant of the thick NaI(Tl) plate, that was developed by Saint-Gobain, called StarBrite® that preserved spatial resolution at low energy for SPECT together with greater thickness providing efficiency for the dual head PET scanner. Mayhugh Decl. ¶ 9. As the year 2000 approached, expressed interest in obtaining from Saint-Gobain a fully-pixilated version of the curved NaI(Tl) detector for a dedicated PET full ring system. Mayhugh Decl. ¶ 9.

During this period, Saint-Gobain focused its PET R&D efforts on NaI(Tl). The first main efforts entailed the development of CurvePlate™ Technology and the aforementioned StarBrite® detectors. Mayhugh Decl. ¶ 10. The measured light response function ("LRF") at low energy of the partially pixelated detector is much narrower than that of a continuous PET detectors, even though the pixelated crystal is thicker, preserving SPECT performance in a device thick enough for PET as well. Mayhugh

Decl. ¶ 10. Sales of the StarBrite® product continue today – including sales to REDACTED Mayhugh Decl. ¶ 10.

4. **The Market Changes.**

With the advent of the 21st century, government decisions affecting the healthcare industry limited the use of dual head PET/SPECT and industry focus turned to dedicated PET machines, a market that has continued to grow. Mayhugh Decl. ¶ 11. Saint-Gobain continued to believe in this time period that NaI(Tl) remained the most promising and robust scintillator material. Through late 2001, Saint-Gobain was focused on supplying NaI(Tl) for PET. Saint-Gobain also began development of two additional materials for next generation PET products: $LaBr_3$:Ce and lutetium pyrosilicate (LPS) (a possible competitor for LSO in the high end market). Mayhugh Decl. ¶ 11. Saint-Gobain was also a limited BGO supplier to Mayhugh Decl. ¶13.

Once again, the contours of the PET market changed dramatically. This time, the change resulted from a series of corporate consolidations among PET scanner manufacturers. Most notably, ADAC bought UGM, Macroni bought Picker, then Philips Medical Systems ("Philips") bought *both* ADAC and Picker/Marconi and REDACTED Mayhugh Decl. ¶ 12. Since that time, the market for PET materials -- including the scintillator detector crystals that Saint-Gobain sells -- has been dominated by three large companies: Siemens Medical, GE and Philips. Mayhugh Decl. ¶ 12.

During this period Saint-Gobain focused on forward-looking prospects and began supplying BGO to the telecommunications (rather than the medical and healthcare) market during the PET ramp-up, REDACTED Mayhugh Decl. ¶13. As a consequence of a dip in the telecommunications market and the changing PET materials market, Saint-Gobain secured patent licenses for cerium-doped lanthanum bromide ("$LaBr_3$:Ce") and cerium-doped lutetium pyrosilicate (Ce: LPS). Despite Saint-Gobain's dedication of considerable time

and resources to this project, Saint-Gobain's "high-Z" (a reference to materials composed of atoms of high atomic number) program, which focused on Ce:LPS, generated insufficient interest among the manufacturers of PET scanners to justify pursuing the program aggressively. Mayhugh Decl. ¶ 14. This was apparently due to the low density of the LPS material. As Dr. McClellan points out in his Declaration, "density" is a highly desirable characteristic for scintillation crystal material. McClellan Decl. ¶ 7. Lanthanum bromide, another crystal with scintillation qualities, seemed initially to offer considerably greater promise. Mayhugh Decl. ¶ 14.

Meanwhile, Saint-Gobain's competition moved ahead in the PET materials market. CTI Molecular Imaging ("CTI") – currently a subsidiary of Siemens, but at the time an independent company -- was selling BGO (and later LSO) to manufacturers and other players in the PET market. This in turn enabled GE to score considerable success selling BGO for PET and PET/CT scanners. Mayhugh Decl. ¶ 13. **REDACTED**

. Mayhugh Decl. ¶ 14.

5. **Time-of-Flight (TOF).**

Time of flight development at Saint-Gobain resulted from **REDACTED** which had proposed to Saint-Gobain a new generation, (TOF) PET, that would utilize a different scintillation crystal, using a Lanthanum Bromide ("La-Bromide") Detector. Mayhugh Decl. ¶ 15. Saint-Gobain enthusiastically committed to the development of this crystal scintillator and invested heavily in La-Bromide to develop reliable and commercially realizable crystals for use in the PET scanners. Mayhugh Decl. ¶ 15. Once again, Saint-Gobain's enthusiasm for this development was primarily driven by the attractive potential of supplying materials to for their incipient (TOF) PET scanners. Mayhugh Decl. ¶ 15.

6. A LYSO License, but for which Patent?

Saint-Gobain added LYSO to its high-Z program R&D even though Saint-Gobain's main effort and focus remained directed at developing $LaBr_3$:Ce scintillators. In order to explore the potential use of LYSO, Saint-Gobain first sought to secure an LYSO license. Mayhugh Decl. ¶16.

The LYSO crystal was the result of a substantial research and development effort at two separate institutions, the Los Alamos National Laboratory and the University of Southern Florida, where separately, researchers at each institution had developed the cerium activated LYSO crystal and successfully pursed patent protection for their inventions. Mayhugh Decl. ¶ 16; McClellan Decl. ¶ 9. Because the LYSO crystal was subject to patent protection, Saint-Gobain pursued a license with the then current patent holder, the Los Alamos National Laboratory, which was the assignee for U.S. Patent No. 6,323,489, a patent that covered a LYSO crystal scintillator. Mayhugh Decl. ¶ 16. As it developed, however, Saint-Gobain learned that two applications had been made on a LYSO scintillator crystal, the '489 patent, assigned to LANL had been granted and the application, which was to become U.S. Patent No. 6,624,420, was assigned to the University of Central Florida (UCF) was pending.

Ultimately, the USPTO declared an interference between the competing patent and application for patent coverage over the LYSO crystal. Notably, both the '489 LYSO patent and the '420 LYSO patent reference the Melcher '080 Patent, the asserted patent here. The USPTO nevertheless found that the crystals claimed in those patent applications qualified for patent protection. Mayhugh Decl. ¶ 16; McClellan Decl. ¶ 11.

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7. **La-bromide or LYSO?**

During the period of uncertainty engendered by the LYSO patent interference proceedings, Saint-Gobain delivered enough La-bromide to to accommodate two PET machines. Mayhugh Decl. ¶17. Notwithstanding the uncertainty respecting the patent protection for the LYSO crystal, adopted a LYSO TOF design based on their GSO machine. Mayhugh Decl. ¶ 18. Saint-Gobain was positioned to become **REDACTED** Marketplace developments also contributed to enthusiasm for choosing the LYSO crystal as the scintillator in new generation of PET TOF scanners. GE, another major supplier of PET scanner equipment had already sold a few LYSO based machines that did *not* have TOF capabilities. Mayhugh Decl. ¶ 18. All these developments contributed to the increased interest in LYSO. As a reciprocal consequence, of course, evinced a lesser interest in having La-Bromide as a scintillator. In addition, neither Siemens nor GE evidenced an interest in La-Bromide scintillators. As a result of these developments in the market for scintillator crystals, Saint-Gobain had no practical alternative but to discontinue its La-bromide R&D for PET and refocus its effort and research and development dollars to developing, producing, processing and distributing superior LYSO for the PET scanners that was developing. Mayhugh Decl. ¶18.

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Siemens Medical's accusation that Saint-Gobain "[urged] at least one of Siemens Medical's medical imaging competitors to incorporate those [LYSO] crystals into infringing PET scanners" is false. It was that urged Saint-Gobain to manufacture LYSO scintillator crystals in order to sell them to -- not the other way around. Having secured -- at instance -- the rights to manufacture, market and sell the patented LYSO crystal, Saint-Gobain next entered into negotiations with ADAC. These negotiations yielded **REDACTED** between Saint-Gobain and pursuant to which Saint-Gobain has agreed to provide LYSO and other materials to

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9. The Impact of this Lawsuit.

Saint-Gobain is not a competitor of Siemens; There are other suppliers of scintillation crystals that could supply the LYSO crystal to , if Saint-Gobain were enjoined. Mayhugh Decl. ¶ 21.

10. The Nature of the LYSO Crystal.

LYSO is not an obvious substitution of a "dash" of yttrium for lutetium as plaintiff claims. It took a great deal of research and experimentation to create the LYSO scintillator. Dr. McClellan investigated several, novel cerium-activated scintillator materials in the Y_2SiO_5- Lu_2SiO_5, Y_2SiO_5-Gd_2SiO_5, and Gd_2SiO_5- Lu_2SiO_5 systems for application in the solid state imaging system. McClellan Decl. ¶6. Based upon Dr. McClellan's experimental results of growth characteristics and scintillator performance weighed against the various overall x-ray imaging system design specifications, McClellan eventually chose to develop a cerium activated Y_2SiO_5- Lu_2SiO_5 solid solution alloy with a 1:9 ratio of the end member compositions. This composition equates directly to the $Lu_{1.8}Y_{0.2}SiO_5$:Ce composition of the accused Saint-Gobain product, as that chemical structure is the basic composition of the Saint-Gobain LYSO scintillator crystal, which Saint-Gobain supplies to under the trade name, PreLude 420. McClellan Decl. ¶6. **REDACTED**

Dr. McClellan chose this composition based upon a combination of criteria designed to obtain four sequential x-ray images in two microseconds from a high energy pulsed x-ray source during an explosive event. Primary scintillator design specifications included a high level of prompt light output, short decay time, relatively high density (>7 g/cm^3), emission wavelength appropriate for a lens-coupled, charge-couple device (CCD) image acquisition system, low optical absorption for the scintillation emission, low afterglow, and relatively low self-excitation, i.e. low background. ^{176}Lu is a naturally occurring radioactive isotope of lutetium with an abundance of ~2.59% which effectively generates a background noise in the detected signal. McClellan Decl. ¶7.

As Dr. McClellan indicates, there is substantial overlap between the scintillator performance characteristics for the DARHT (Dual-Axis Radiographic Hydrodynamic Test) facility application for explosive conditions, for which Dr. McClellan developed LYSO, and for use in a PET scanner. These characteristics include emission wavelength compatible with the rest of the imaging system, high effective atomic number to provide a high probability of the x-ray or gamma ray interacting with the scintillator crystal, high quantum efficiency so that a large amount of light is generated from an interaction and that light is able to escape the crystal into the rest of the imaging system, fast decay of the scintillation light for timing, and low afterglow so that the emission signal is not lost in the background signal. McClellan Decl. ¶ 7.

In addition to the optical performance characteristics, suitability to efficient growth of high quality single crystals from the melt was also a major factor in selecting the scintillator composition for development. Suitability for efficient growth means that the crystals can be grown in large sizes (≥ 5 centimeters (cm) in diameter, with total lengths on the order of 30 cm or longer), with a high yield of material possessing the required performance characteristics (the scintillation properties vary along the length of a given crystal so typically only a fraction of a grown crystal is usable), and that this can be achieved in an economical operation (rare earth oxyorthosilicate crystal growth is relatively expensive due to the cost of 1) high purity, raw powders, 2) precious metal components to contain the molten compound, 3) high temperature insulation materials required for these crystals with melting points of ≥2000 °C, 4) the energy required to perform crystal growth at temperatures ≥2000 °C, and 5) the large waste associated with crystals that are damaged or that do not meet performance specifications. Therefore both performance and manufacturing issues are important for scintillator crystals the PET market of any commercial application requiring large quantities of scintillator crystal (tens of kilograms of crystal per unit). McClellan Decl. ¶ 8.

Dr. McClellan's research team did substantial development of the $Lu_{1.8}Y_{0.2}SiO_5$:Ce scintillator crystal. As a result of an application to the USPTO, Dr. McClellan was granted a patent, US 6,323,489, a true copy of which is attached as an exhibit to Dr. McClellan's Declaration (the '489 Patent). The '489 Patent was originally assigned to the Regents of the University of California for scintillator crystals with the composition of $Lu_{(2-x-z)}Y_xCe_zSiO_5$ where $0.05 \leq x \leq 1.95$ and $0.001 \leq z \leq 0.02$ and the use of those crystals in a detector. McClellan Decl. ¶9. Some aspects of the development of this crystal were presented in open meetings and originally published in 2000. McClellan Decl. ¶ 9.

As a result of a provisional patent filed by B. Chai and Y. Ji, the USPTO declared an interference with the '489 patent. Due to technical reasons associated with patent law US 6,323,489 was ultimately surrendered and patent US 6,624,420 was issued covering the relevant compositions. McClellan Decl. ¶9. The $Lu_{1.8}Y_{0.2}SiO_5$:Ce scintillator crystal, covered by the '420 Patent has been licensed to Saint-Gobain and is the basis for Saint-Gobain's Prelude 420 product. McClellan Decl. ¶ 9.

As detailed in the McClellan Declaration, the creation of the LYSO crystal does not represent an insubstantial change over the LSO crystal, and, based upon the patents granted on this crystal, the USPTO agrees. There are substantial advantages over LSO in terms of performance and manufacture for the use of the LYSO crystal. For example, the $Lu_{1.8}Y_{0.2}SiO_5$:Ce (LYSO) scintillator crystal has substantial advantages over LSO in terms of: 1) the ability to tailor performance characteristics relative to the "pure" end member oxyorthosilicates, i.e. YSO and LSO, 2) the ability to improve manufacture of the scintillator crystal relative to the end members, and 3) the critical role of crystalline lattice defects (imperfections in atomic type and position relative to an "ideal" arrangement of atoms within the crystal structure) on scintillator performance. McClellan Decl. ¶ 11. The ability to tailor scintillator performance and to balance that performance against fabrication considerations is one of the reasons that the LYSO composition is considered as a unique scintillator material. McClellan Decl. ¶ 11.

When considering combining elements to make new materials, the combinations are effectively infinite. Therefore, it is often convenient to view compositions in terms of "end members," and these end members can be the individual atomic constituents or compounds themselves. McClellan Decl. ¶ 12. For instance, at the most basic level, under normal pressures, the end members of the binary compositional systems Y-O, and Si-O can be combined in the ratios of 2:3 and 1:2, respectively, to form Y_2O_3 and SiO_2. Various combinations of Y_2O_3 and SiO_2 can then be formed with new compounds being formed at specific compositions, e.g. a 1:1 ratio will form Y_2SiO_5 (YSO). This can be considered as a pseudo-binary system where the compositions effectively fall on a line between the end members (Fig 1a).

A more complex representation of the combinations of these elements would be the Y-Si-O system where compositions fall within a triangle bounded by the end members, Y, Si, and O (Fig 1b). The three compounds indicated are relevant to the current discussion but are in no way the only ones that exist in this three element system. The area contained within the triangle in figure 1b illustrates the continuum of compositional possibilities in even this simple system. A similar representation could be made for the Lu-Si-O system that contains LSO. Within a given compositional space, materials can form new compounds with atomic arrangements different from the end members, such as the $Y_2O_3SiO_2$, and Y_2SiO_5 compounds indicated, or they can form mixtures of the end members which herein are referred to as solid solutions or alloys. As the number of components in a chemical system increases the

Fig 1a)

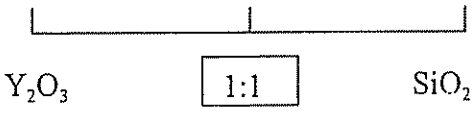
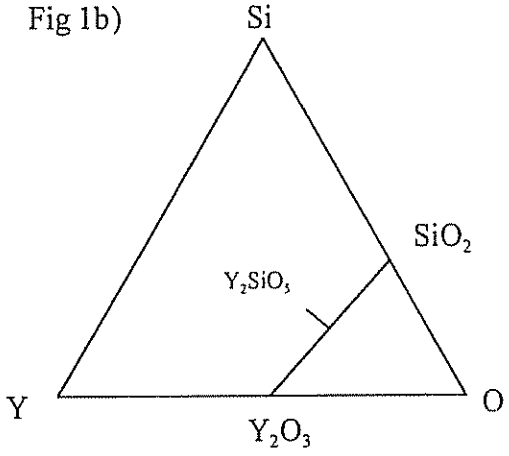


Fig 1b)



compositional possibilities increase accordingly. The compositions that correspond to discrete structures and those that correspond to mixtures are not known *a priori* and the individual properties of any given composition are not known until it is made and tested. McClellan Decl. ¶13.

In description of these crystals, the Y-Lu-Ce-Si-O system is simplified as a pseudo-binary system of Y_2SiO_5:Ce and Lu_2SiO_5:Ce, i.e. YSO-LSO. McClellan Decl. ¶ 14. By pseudo-binary, as Dr. McClellan uses the term, the complexity of a crystal is obscured by the identification of only two of the elements. In the range of compositions between YSO and LSO there are no known phases with a different crystal structure so each composition will have its own characteristics, some of which will be similar to an end member, some of which may be some combination of the end member characteristics and some of which may be completely different. For solid solutions no characteristic is likely to be exactly the same as that for an end member. The view that the solid solutions in the rare earth oxyorthosilicate crystals are unique crystal compositions is supported broadly in the field of material science but particularly by the technical articles discussing the relative merits of the crystals in the various LSO-GSO-YSO pseudo-binary systems (i.e. LSO-GSO, LSO-YSO, and GSO-YSO, as well as several existing US patents which claim unique end member and solid solution compositions in the family of rare earth oxyorthosilicate compounds). McClellan Decl. ¶14.

Contrary to Siemens' current claims that LYSO is equivalent to LSO, one of the most telling examples supporting the existence of LYSO as a unique scintillator composition is shown in the paper entitled "Investigation of the properties of new scintillator LYSO and recent LSO scintillators for phoswich PET detectors" which is co-authored by Charles L. Melcher, the inventor of the '080 patent, and specifically describes a LYSO solid solution composition as a *new* scintillator. See, McClellan Decl. ¶ 15. The authors, including the named inventor of the '080 Patent state: "A variant of LSO in which some of the lutetium is replaced by yttrium atoms has recently been developed at CTI, Inc.

(Knoxville, TN)[8]. Cerium-doped lutetium-yttrium oxyorthosilicate ($Lu_{0.6}Y_{1.4}SiO_5$:Ce, LYSO) has comparable light yield to LSO with a slightly longer decay time of 53 ns (ns is the abbreviation for a nanosecond or 1/1,000,000,000th of a second), making it an attractive candidate for PSD identification in phoswich detectors. In this work, the scintillation performance of the *new LYSO scintillator* (emphasis added) was investigated...and compared to the most recent LSO production." Another example arguing for the unique existence of solid solution scintillator compounds is US patent 5,264,154 which claims cerium-activated scintillator crystals represented by the formula $Gd_{2-(x+y)}Ln_xCe_ySiO_5$ where Ln is at least on element of Sc, Tb, Dy, Ho, Er, Tm, Yb, and Lu with contents ranging from $0.1 \leq x \leq 0.7$, i.e. LGSO is claimed where the gadolinium in the end member composition GSO is replace by 10 atomic percent or more of lutetium. Again here C. L. Melcher is a co-inventor of this range of new scintillator crystals. McClellan Decl. ¶15.

The conclusion that the LYSO scintillator is a new and not insignificant scintillator is consistent with the established understanding in the field of material science that the compositions intermediate between two chosen compositional end points will exhibit some properties that are similar to an end member and some properties that are different from the end members. McClellan Decl. ¶ 16. Many properties change gradually, but based on Dr. McClellan's experience in materials science, the statement that 10 mole percent of yttrium with respect to the rare earth elements in the oxyorthosilicate structure ($Lu_{1.8}Y_{0.2}SiO_5$:Ce (90/10 LYSO)) substitutes "a small amount of lutetium in the LSO crystals claimed in the'080 patent with a *dash* (emphasis added) of another rare earth element (yttrium) that has similar properties" as stated in the Plaintiff's opening brief is not a correct statement. McClellan Decl. ¶16.

In the field of scintillator crystals, substantial performance differences are often associated with activator or impurity contents at the levels of several parts per million (ppm). McClellan Decl. ¶ 17. This is especially true of the rare earth elements (including Ce, Lu and Y) as they are associated with a

[8] CTI Inc. is a predecessor of plaintiff Siemens Medical Solutions USA, Inc. McClellan Decl. ¶ 15, FN 3.

large fraction of the optical materials developed for technical applications, e.g. lasers and scintillators. McClellan Decl. ¶ 17. Indeed, as the Declaration of Dr. McClellan indicates, the cerium activator that dopes the LYSO scintillator crystals is included at the ppm levels. On the other hand, the yttrium content in the PreLude 420 scintillator is ~10 % which equates to ~100,000 ppm, a level three to four orders of magnitude higher than the enabling Ce activator in the same crystal. McClellan Decl. ¶ 17.

The characteristics of a given composition can be estimated based upon experience and intuition but cannot be definitively predicted. McClellan Decl. ¶ 18. For instance, due to the cost and difficulty in getting raw, highly pure lutetium oxide powders for crystal growth, industry and researches have continuously sought to find other rare earth compositions for a given application. In the area of rare earth oxyorthosilicates, two promising candidates La_2SiO_5:Ce and Yb_2SiO_5:Ce were considered. La_2SiO_5:Ce crystals were not even able to be grown using standard techniques. McClellan Decl. ¶ 18. Attempts to use the related rare earth lattice element ytterbium, which is similar to Lu in many characteristics, inasmuch as it is adjacent to lutetium in the periodic table, showed successful growth of the single crystals but the Yb suppressed the Ce emission in the oxyorthosilicates, via a parasitic charge transfer which quenches the light output, i.e. the crystal was transparent and dense but not bright. McClellan Decl. ¶ 18. These characteristics are undesirable for an effective scintillation crystal.

Accordingly, while yttrium was readily anticipated to be a viable lattice constituent based on the success of YSO scintillators, the success of the LYSO scintillator was not known until the crystal had been made and tested. McClellan Decl.¶ 19. The mixture of Y^{3+} and Lu^{3+} ions in the LYSO distorts the structure relative to either of the end member compositions, LSO and YSO. Specifically, the yttrium in LYSO can be considered to "open up" the crystalline lattice relative to LSO due to its large atomic size. McClellan Decl. ¶19.

The effect of defects in a given class of scintillator crystals is not sufficiently understood as to be able to be predictive in terms of scintillator performance, especially in such complex crystalline

structures as the rare earth oxyorthosilicates. McClellan Decl. ¶ 21. The individual single crystal compositions must always be grown and characterized to establish such key scintillator characteristics as total light output, the fraction of light which occurs as prompt emission, the decay time, and the existence and magnitude of afterglow. McClellan Decl. ¶ 21.

The addition of yttrium as an atomic substitution, contrary to Siemens' assertion, would in fact substantially affect the character of the scintillator relative to that of LSO. This is shown by the prior development of LYSO for national security applications and the broad acceptance of LYSO as a unique scintillator. McClellan Decl. ¶ 23. In addition, while it is true that some important properties for PET scanners are very similar in LSO and LYSO (as well as YSO), it is incorrect to represent that the LYSO solid solution of the LSO and YSO end member compositions is functionally equivalent to LSO. McClellan Decl. ¶ 23. The incorporation of yttrium atoms into the oxyorthosilicate structure at the 10 atomic percent level (PreLude 420) level will perturb the lattice relative to the end member compositions enabling tailoring of specific properties such as background optical emission due to naturally occurring radioactive isotope, prompt emission light output, afterglow, and density. Indeed the advantages of YSO and LYSO relative to LSO in terms of detrimental afterglow is the subject of a recent patent for performance improvements in LYSO. McClellan Decl. ¶ 23.

By way of example, the effects of yttrium incorporation in terms of rare earth cation distribution in the C2/c oxyorthosilicate structure (the general structural arrangement of atoms shared by YSO, LSO, and LYSO), can be examined more closely. Due to the difference in atomic size between Lu, Y and Ce, it is expected that LYSO compositions allow site occupancy to be biased to favor a non-random distribution of cations (Lu^{3+}, Y^{3+}, Ce^{3+}, Ce^{4+} on the two non-equivalent rare earth cation sites (RE1 and RE2)). McClellan Decl. ¶ 24. This ability to bias site occupancy and corresponding defects associated with the lattice perturbations in these activated, solid solution compounds can manifest itself in the emission spectrum, decay time, prompt light output and afterglow. McClellan Decl. ¶ 24. Dr.

McClellan believes that these site occupancy bias effects are seen in the optical emission data presented in Doshi's affidavit, submitted in putative support of Siemens' application. The "shoulders" on the emission curves in his Exhibit G show increased light output relative to the LSO. This shoulder is in the region of emission from the second rare earth site in the oxyorthosilicate structure (RE2) and not only provides additional light output from the crystal but also shifts the average emission to a slightly longer wavelength. McClellan Decl. ¶ 24.

Yttrium-bearing solid solutions have advantages over LSO in terms of manufacture via reductions in growth costs per single crystal boule and yield of high quality material per boule. As Dr. McClellan details, yttrium "opens up" the lattice relative to LSO which increases the incorporation of Ce (a larger cation) into the boule enabling a increased yield of high quality crystal per growth. The yttrium also suppresses the melting point relative to LSO which provides energy savings as well as savings from decreased attrition of structural components used for crystal growth. There exists a better infrastructure for manufacture of high purity yttrium oxide powder on a world-wide basis, a fact that translates to lower raw material cost and to reduced issues associated with material impurities. McClellan Decl. ¶ 25. With this combination of the ability to tailor LYSO's optical performance and the advantages in large scale manufacturing it can readily be seen why this unique scintillator is a compelling choice for the PET market.

In summary, the LYSO scintillation crystal, and particularly Saint-Gobain's composition for fabrication of Saint-Gobain's PreLude 420, 1) is a unique scintillator crystal with distinct and substantial advantages over the LSO crystal, 2) has distinct, substantial differences and advantages in terms of optical performance and in terms of manufacture, and 3) is not simply an equivalent, insubstantially interchangeable crystal with regard to application in PET scanners.

ARGUMENT

I. SIEMENS FAILS TO SATISFY ALL THE ELEMENTS REQUIRED TO OBTAIN THE EXTRAORDINARY REMEDY OF A PRELIMINARY INJUNCTION.

A. Siemens Has No Substantial Likelihood Of Success On The Merits Of Its Application For Injunctive Relief Because The Patented LYSO Crystal, Accused Of Infringing The '080 Patent Is Not Equivalent To The LSO Scintillating Crystal

The standards for preliminary injunctive relief are well known to this Court and scarcely bear repetition or argument:

1) Substantial likelihood of success on the merits;

2) The presence of irreparable harm;

3) A balance of equities favoring the grant of the injunction;

4) The public interest.

Saint-Gobain will discuss each of these in turn although Saint-Gobain focuses principally on those elements that demonstrate most compellingly that Siemens is entitled to no relief whatever, requiring the denial of the motion Siemens has brought.[9]

1. Siemens Claims Only Infringement By The Doctrine Of Equivalents.[10]

The first of these elements poses an insuperable hurdle for Siemens to overcome. Siemens bears the very considerable burden of demonstrating that it has a substantial likelihood of success on the merits

[9] For example, for purposes of this preliminary injunction hearing, Saint-Gobain has chosen not to contest whether there are other uses to the patented LYSO crystal, thereby making it a staple of commerce with a substantial non-infringing use. That issue, however, is open for final resolution at trial. Similarly, Saint-Gobain has not launched a direct attack on the validity of the '080 patent at this early stage, without, however, conceding the validity of the asserted patent. In the interest of focusing the Court on the central issues of this application, Saint-Gobain has restricted its rebuttal of Siemens' efforts to those areas where the utter lack of merit to this application is most manifest.

[10] Because Saint-Gobain does not manufacture or sell the PET Scanner into whose structure the LYSO crystal is incorporated that Saint-Gobain does supply Saint-Gobain can be charged only with contributory or inducing infringement. The proofs here show that urged Saint-Gobain to explore, manufacture and supply the LYSO crystal, making "inducement," which requires intent on Saint-Gobain's part to persuade to use the crystal in this context, an impossible burden for Siemens to satisfy. Although Saint-Gobain will contest the contributory charge on the merits at trial, at this preliminary stage, Saint-Gobain limits the scope of its defense to the showing that there can be no direct infringement because the patented LYSO crystal is not the equivalent of the LSO crystal.

in this patent infringement case. *See, e g , Solarex Corp v. Advanced Photovoltaic Sys., Inc,* 1995 WL 314742 (D. Del 1995); *Digene Corporation v. Ventana Medical Systems, Inc.*, 2007 WL 1364401 (D. Del 2007); *Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.* 235 F.Supp. 2d 390 (D. Del 2002). The difficulty of this burden is heightened because Siemens concedes that there is no literal infringement of the '080 Patent. In its endeavor to sustain its obligation to show a likelihood of success on the merits, Siemens urges that the LYSO crystal that Saint-Gobain manufactures is nothing more than an insubstantial equivalent to the LSO crystal that is the subject of the '080 Patent.

2. Saint-Gobain's Patented LYSO Crystal Is Entitled To Be Presumed Nonobvious And Therefore Not An Insubstantial, Equivalent To The Crystal Of The '080 Patent.

Siemens' application for the extraordinary remedy of a preliminary injunction founders on the bedrock requirement to show the 'equivalence' of Saint-Gobain's patented LYSO crystal to the crystal claimed in the '080 Patent. The reason for this conclusion is straightforward. It is indisputable that the LYSO crystal, whose incorporation into a PET scanner is alleged to contribute to the alleged direct infringement by of the '080 Patent, is itself the subject of a separately issued United States Patent, the '420 Patent. McClellan Dec. ¶9. Indeed, as both the McClellan and Mayhugh Declarations make clear, the USPTO granted a patent to Dr. McClellan respecting the LYSO crystal before declaring an interference between Dr. McClellan and the inventors of the crystal claimed in the '420 Patent. McClellan Dec. ¶9; Mayhugh Dec. ¶16. That interference proceeding ended with the USPTO awarding the patent to Chai et al. McClellan Dec.¶9. The USPTO granted this patent even in the face of the existence of the '080 Patent, which was cited during the prosecution, and over which the examiner nonetheless granted the patent. Mayhugh Dec. ¶16

Thus, the LYSO compound over which Siemens has spilled so much ink in its effort to persuade this Court that LYSO is a mere, insubstantial equivalent to the LSO of the '080 Patent has twice been found to qualify independently for patent protection.

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As the Federal Circuit has only recently recognized, "... [t]here is a strong argument that an equivalent cannot be both non-obvious and insubstantial." *Festo Corp. v. Shoketusu Kinzoku Kogyo Dabushiki Co. Ltd.*, 493 F.3d 1368, 1380 (Fed. Cir., 2007)(footnotes omitted). Put more directly, if the '420 Patent is valid as a non-obvious invention, as it must be presumed to be by operation of law, then the addition of 10% yttrium to the LSO compound cannot logically be "insubstantial" to justify a finding of equivalence. *Id*

Siemens' equivalence argument is thus substantially eroded by the fact of the grant of the '420 Patent. At a minimum, the grant of the '420 Patent, which is itself entitled to the same presumption of validity that attaches to the '080 Patent, means that the USPTO has recognized that the LYSO crystal has satisfied the requirements of the Patent Act to be non-obvious. Indeed, the issuance of a later patent on a device or compound that is later accused of infringement is highly relevant to an issue of equivalence, for "the PTO must have considered the accused product to be nonobvious with respect to the [previously] patented composition." *Hoganas AB v. Dresser Industries, Inc.* 9 F.3d 948 954 (Fed. Cir. 1993).[11]

There is no question that the Federal Circuit has "not directly decided whether a device---novel and separately patentable because of the incorporation of an equivalent feature---may be captured by the doctrine of equivalents, although we have held that when a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, *is at least considerably more difficult to make out*." *Festo Corp. v. Shoketusu Kinzoku Kogyo Dabushiki Co. Ltd.*, 493 F.3d 1368, 1380 (Fed. Cir. 2007)(footnotes

[11] Another misleading aspect to Siemens' presentation is its reliance on the fact that the wave length of light emitted by either the LSO or LYSO crystal is approximately the same. Of course it is: both are activated by cerium, and the active dopant dictates the wave length of the emitted light.

omitted)(emphasis supplied). And Saint-Gobain does not ask this Court today to make either that holding or to advance the law to this point.[12]

The Federal Circuit has accordingly recognized that the burden is greater to make the factual showing of equivalence under the doctrine of equivalence where, as here, the accused compound is itself the subject of a patent that was issued by the USPTO. At a minimum, "the issuance of [a patent on an allegedly 'equivalent' compound] is relevant to the equivalence issue." *Hoganas AB v. Dresser Industries, Inc.* 9 F.3d at 954. Indeed, Saint-Gobain's patented LYSO crystal should be "presumed nonobvious" and the "nonobviousness . . . relevant to the issue of whether the change therein is substantial." *Zygo Corp. v. Wyko Corp,* 79 F.3d 1563, 1570 (Fed.Cir. 1996). The burden on Siemens should be all the greater where, again as here, the asserted patent was itself already considered by the USPTO as prior art during the examination of the patent on the currently accused device. What Siemens endeavors to do here, in effect, is have this Court declare, on a preliminary injunction application, on a less than complete record, within months of the filing of this action that the '420 Patent is not entitled to the presumption of validity. That is the error that Siemens invites this Court to make.

3. *Graver Tank,* Properly Read, Supports The Denial, Not The Grant Of Siemens' Application

In its effort to stretch the bounds of the '080 Patent's claims Siemens relies substantially on *Graver Tank & Mfg. Co., Inc. v. Linde Air Products,* 339 U.S. 605 (1950) for its argument, arguing that the present case is indistinguishable from *Graver Tank.* Siemens' argument is substantially misplaced, for Siemens' reading of the snippets from *Graver Tank* Siemens quotes obscure the fact that *Graver Tank,* properly read, supports the denial of Siemens' application. In *Graver Tank* the Court said, in part:

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[12] Saint-Gobain concedes that the law does not yet hold that "if there is an issue of 'insubstantial' change with respect to equivalency, separate patentability does not automatically negate infringement." *Glaxo Wellcome, Inc. v. Andrx pharms., Inc.,* 344 F.3d 1226-33 (Fed.Cir. 2003), but the fact of this later, separate patent is powerful evidence for the Court to consider. *Id.* Indeed, on a *preliminary* injunction application, the fact that the accused compound has been granted a patent is very substantial evidence that negatives the substantiality of plaintiff's likelihood of success on the merits.

> What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case. Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum.

Id. at 609. Nothing could be clearer or more apt: an understanding of equivalence in any one case depends powerfully on the factual context of the matter under consideration. Generalities often mislead---as Siemens' argument itself demonstrates. The context of *Graver Tank* was that the substituted element was conceded generally in the literature of welding fluxes to be equivalent. The accused compound was neither patented nor was there "evidence of any kind to show that [the accused product] was developed as the result of independent research or experiments." *Id.*, at 611. These facts justified in part the Supreme Court's affirmance of the trial court's finding of equivalence. *Id.*

The facts before this Court on the current application are worlds apart from those upon which the District Court in *Graver Tank* relied to find equivalence. Here, as Dr. McClellan describes in specific detail, the LYSO crystal was created through the hard work of experimentation and scientific effort, precisely of the sort that characterizes the kind of innovation that precedes the grant of an invention, worthy of patent protection, as the USPTO recognized in the scintillation crystal setting by granting a patent over the LSO crystal. *See, Hoganas AB v. Dresser Industries, Inc.* 9 F.3d at 954 (Fed. Cir. 1993).

The specification of the '080 Patent itself contradicts the suggestion that Siemens makes here that the substitution of yttrium for certain lutetium atoms in the LSO compound would be an insubstantial substitution. In describing the uncertain and unpredictable nature of the "rare earth" compounds, the '080 Patent recites that "it was not at all clear whether the luminescence properties or other properties of the single crystal for of a rare earth compound would be the same as those of the phosphor form. *Generally, in fact, the scintillation properties of single crystal scintillators are not readily determinable or predictable with certainty in advance from the phosphors.*" '080 Patent, Col. 3, ll. 1-7 (emphasis supplied). Even Dr. Weber, Siemens' proposed expert, agrees that only experimentation is the true

crucible of hypothesis, especially with the rare earths, whose properties are only recently becoming better understood. Weber Dep. Transcript at 17: 15-18:15.

4. The Record Amply Supports The USPTO's Implicit Finding Of Novelty And Substantial Difference Between The Patented LYSO Crystal And The Patented LSO Crystal By Showing A Vast Array Of Substantive Advantages For LYSO.

The Record here is replete with evidence of the effort that went into the development of the LYSO crystal, culminating in its being patented. *See,* McClellan Decl. ¶¶6-9. In addition, and directly contrary to the malevolent descriptions that Siemens endeavors to place on Saint-Gobain's development of the LYSO crystal, Saint-Gobain did not spy out the LSO crystal and then, as the defendant in *Graver Tank* apparently did, make a simple and insubstantial substitution in order to create the compound now accused of infringement. Rather, Saint-Gobain was urged by its customer, , to pursue the development of the LYSO crystal, thereby abandoning all the work that Saint-Gobain had already done on a La-bromide crystal for which Saint-Gobain had had high expectations.

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Further, again unlike the defendant in *Graver Tank,* Saint-Gobain recognized that the scintillation crystal that its customer wanted supplied to it was subject to patent protection, controlled by another, and Saint-Gobain obtained a license to assure rights to fabricate and sell that scintillating crystal. Mayhugh Dec. ¶16.[13] Saint-Gobain obtained rights to manufacture and sell the LYSO crystal, and has done so ever since, not infringing on the '080 Patent, but rather, practicing another, valid U.S. Patent, the '420 Patent, granted for a separate and patentably distinct compound.

The USPTO's conclusion to grant a patent on the LYSO crystal in the '420 Patent, under which Saint-Gobain makes and sells its LYSO crystal, is further supported by the observations and conclusions of Dr. Kenneth McClellan, whose Declaration details the qualities and characteristics of the LYSO

[13] Having first negotiated with one patent holder, only to learn that another applicant had senior rights to the invention and thereby secured a patent over the rights of the entity with whom Saint-Gobain originally negotiated, Saint-Gobain then negotiated and executed a license with the later patentee. Rather than acting in the brazen manner, suggested by the harsh rhetoric of the Siemens' brief, Saint-Gobain's behavior with respect to developing the LYSO crystal was a paradigm of how entities operate to honor the intellectual property rights of others.

crystal that point to the conclusion that the LYSO crystal is in truth *not* the mere equivalent that Siemens postures it to be. In fact, Dr. McClellan articulates in specific and expansive detail the many distinctions and advantages that the LYSO crystal offers over the LSO crystal. It would unduly lengthen this brief to recount them all again in this argument section. They are, however, elaborated in the Statement of Facts. The description found there, fully supported by the McClellan Declaration, puts the lie to Siemens' argument that LYSO somehow is an insubstantial equivalent of LSO. From Dr. McClellan we learn, in a nutshell, that the addition of the yttrium atom, supplanting certain lutetium atoms in the atomic structure stretches the matrix of the crystalline lattice to increase the probabilities that emitted light can escape, one of the goals of the PET scanner technology and is just one key advantage to the operation of the LYSO crystal as a scintillation crystal in a PET Scanner.

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6. Prosecution History, Relevant To The '080 Patent, May Further Limit The Legitimate Reach Of The Doctrine Of Equivalence For The '080 Patent.

There is even a threshold question whether Siemens is even entitled to lay claim to a range of equivalents to the LSO crystal of the '080 Patent. In *Festo Corp. v. Shoketusu Kinzoku Kogyo Dabushiki Co. Ltd.*, 344 F.3d 1359, 1367 (Fed.Cir. 2003)(en banc), the Federal Circuit detailed a four part test to determine whether prosecution history limited the scope of a claim under the Doctrine of Equivalents. The test requires a demonstration that 1) there was a narrowing amendment to a claim during prosecution, 2) the narrowing amendment was made for reasons related to patentability, 3) creating a rebuttable presumption that there was a surrender of claimed territory that cannot be recaptured by resort to the Doctrine of Equivalents and 4) failure to rebut the presumption, surrenders the equivalents.

In a parent application to the application that resulted in the '080 Patent, the applicant amended Claim 1 to narrow the claimed scintillator to be a "transparent" scintillator. Further, the Claim was amended to reduce and specify the concentration of cerium in the crystal, as opposed to the melt crystal. The precise ranges of the reduced requirements of cerium in the crystal are not as significant as the fact that both these amendments were made to overcome USPTO rejections of Claim 1 on the basis of indefiniteness, a rejection related to patentability. These facts related to the prosecution history of the '080 Patent create the presumption that Siemens is entitled to little if any range of equivalents to the '080 Patent.[14]

The equitable maxim that to doubt is to deny holds particularly compelling attraction here. At this preliminary stage, where Saint-Gobain has cast substantial doubt as to the merit of Siemens' core argument, that the patented LYSO crystal is the 'equivalent' to the LSO crystal of the '080 Patent, this Court should proceed with commendable caution and deny the application.

B. Siemens Suffers No Irreparable Harm In Permitting Saint-Gobain To Continue The Manufacture And Sale Of The LYSO Crystal For Use In A PET Scanner.

Siemens makes the facile equation that proof of patent infringement equals irreparable harm. But, especially since *eBay Inc. v. Mercexchange, L.L.C.*, 2006 U.S. Lexis 3872 (2006), any suggestion that there are automatic rules respecting the grant or denial of injunctions, such equations are at best questionable. *Id.* at ***10-11 ("the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and ...such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." Thus, the four-fold test for injunctions was reinforced in *eBay*. Under that traditional test, Siemens has no claim to irreparable harm. As Justice Kennedy noted, "Both the terms of the Patent Act

[14] It matters not a whit that the amendments were made in a parent application. The Federal Circuit has long foreclosed a patentee's effort to evade an earlier prosecution history estoppel in parent application by filing a continuation. *Jonsson v The Stanley Works*, 903 F.2d 812, 818, 821 (Fed.Cir. 1990). Siemens is bound to those amendments for purposes of the '080 Patent.

and the traditional view of injunctive relief accept that the existence of a right to exclude does not dictate the remedy for a violation of that right." *eBay*, at ***12.

First, enjoining Saint-Gobain would not exclude competitor from the marketplace, for there are other suppliers of the LYSO crystal available to were Saint-Gobain enjoined from supplying Weber Dep. Trans. at 106:11-107:16.[15] The proposed injunction would visit commercial harm on Saint-Gobain without benefiting Siemens by excluding a competitor.

Second, with less than a year before the '080 Patent expires, and with the sales of the LYSO crystal having begun scarcely more than a year before this action began, the availability of money damages will more than fairly compensate Siemens in the unlikely event, after trial, that Siemens prevails.

II. BOTH THE PUBLIC INTEREST AND THE BALANCE OF EQUITIES FAVORS SAINT-GOBAIN.

The accused product, a PET Scanner for which Saint-Gobain supplies the scintillation component, is a medical device that provides information about the body's chemistry not available through other procedures. Unlike CT (computerized tomography) or MRI (magnetic resonance imaging), techniques that look at anatomy or body form, PET studies metabolic activity or body function and has been used primarily in cardiology, neurology, and oncology. For example, PET scans have been used to assess the benefit of coronary artery bypass surgery, identify causes of childhood seizures and adult dementia, and detect and grade tumors. To the extent that any injunction would foreclose delivery of such devices to the public, this is an equity that favors Saint-Gobain.

Courts are loath to enjoin devices that promote public health, especially medical devices. For example, in *Cordis Corp. v. Boston Sci. Corp.*, 99 Fed. Appx. 928, 935-936 (Fed. Cir. 2004), the Federal Circuit affirmed this court's denial of a preliminary injunction against defendant's allegedly infringing

[15] Only a successful suit against has the potential to assure Siemens the ability to exclude a competitor.

coronary stints, holding that "a strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either" the patented or the allegedly infringing stent. *Id.* at 935.

The Federal Circuit also has affirmed this Court's weighing the fact that professionals preferred the accused product over the patented product. *Id.* at 935; *see Datascope Corp. v. Kontron, Inc.*, 611 F. Supp. 889, 895 (D. Mass. 1985), *aff'd*, 786 F.2d 398 (Fed. Cir. 1986) (the court held that the public would be harmed by an injunction because some physicians prefer the defendant's product).

Further, in *Ethicon, Inc. v. United States Surgical Corp.*, 1992 U.S. App. LEXIS 8823 (Fed. Cir. 1992), the Federal Circuit again affirmed a district court's denial of a preliminary injunction on an allegedly infringing medical device, finding that the public's need for the allegedly infringing trocar (a device used to punctures the skin and allow for insertion of other instruments into a body cavity in order to perform minimally invasive surgical procedures) could not be met by the patented trocar. There, the defendant made "special" trocars out of "radiolucent materials which [were] not in [plaintiff's] product line. *Id.* at 4.

Here, the public interest weighs strongly in favor of Saint-Gobain Ceramics and Plastics, Inc., because 1) several professionals in the industry have shown a preference for the LYSO crystal over the LSO crystal scintillators, 2) the LYSO crystal is used along with the LSO crystal in checkerboard scintillators, where both types of crystals are required for research, and 3) the LYSO crystal offers an important "time-of-flight" image correlation feature at a more affordable cost than the LSO crystal, 4) as stated in the McClellan declaration, LYSO is a unique scintillator crystal that has distinct differences (and advantages) in terms of optical performance and in terms of manufacture over LSO. McClellan Decl. ¶ 26. LYSO has proven to be a valuable component of crucial technology in the medical community by offering a cost efficient method for time-of-flight applications and future applications yet to be developed.

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A. **The Balance Of Equities Favors Saint-Gobain.**

The foregoing points make clear that balancing the equities of this action favor retaining the status quo here by withholding injunctive relief on a preliminary basis, to permit Saint-Gobain to supply the scintillation component for some of PET Scanners. In *Ethicon,*, the Federal Circuit affirmed the district court's denial of injunctive relief where, as here, the effect of a preliminary injunction on defendant's long established business would be "devastating." *Id.* at 3. As Siemens alleges here, plaintiff's only harm there was "the asserted difficulty in penetrating the market established by [defendant] . . . ." *Id.* at 3. The Federal Circuit agreed this was insufficient.

Here, as in the cases above, the balance of hardships weigh heavily in the defendant's favor. As the Mayhugh declaration explains, Saint-Gobain began working with LYSO after being induced by to work on PET time-of-flight LYSO scintillators. At urging, Saint-Gobain invested a large amount of research and development money into growing and selling LYSO scintillators. When approached Saint-Gobain with its idea for a LYSO TOF PET, Saint-Gobain was ready with a LYSO license to begin producing LYSO scintillators. Currently, selling LYSO scintillators for TOF PET is a major business for Saint Gobain. An injunction at this point would destroy Saint Gobain's place in the business it created. However, Siemens only harm if the injunction is not granted would be the asserted difficulty in penetrating the TOF PET market established by This, too, is insufficient.

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As previously noted, any injunction against Saint-Gobain would not assure Siemens of the relief it claims to need, assurance against the competition of another PET Scanner manufacturer that employs the LYSO crystal. Saint-Gobain is not the only supplier of LYSO. Even Siemens' proposed expert witness, Dr. Weber, acknowledged the existence of other suppliers. Therefore, eliminating Saint-Gobain as a LYSO producer will not eradicate LYSO from the scintillator market as plaintiffs claim, rather it

will needlessly destroy Saint-Gobain's business, a business Saint-Gobain succeeded in making for itself after several attempts to anticipate the market in PET scintillators.

When Saint-Gobain prevails at trial on the ultimate merits, the damage done by an injunction now to its burgeoning business would likely not be adequately compensated by money damages. Saint-Gobain would have to close down its manufacturing of LYSO and thereby forfeit its foothold in the LYSO scintillator market to either CPI or CTI, Saint-Gobain's competitors.

Finally, the fact that the patent will expire in less than a year is further reason to deny the relief in that a preliminary injunction is, in the context of this case, truly a permanent injunction for the remaining life of the patent. Siemens' motion for a preliminary injunction is its attempt to use the legal system to secure a monopoly beyond that contained in the LSO patent by extending the patent's scope to cover the LYSO scintillator, a crystal the USPTO has twice determined is novel, useful, and nonobvious, and as Dr. McClellan demonstrates in his declaration, not a mere improvement over LSO. Saint-Gobain should not be made to shoulder the cost of losing this business as a result of a preliminary injunction because Siemens lost its innovative edge in the marketplace.

Siemens' motion should be denied in all respects.

CONCLUSION

For the foregoing reasons, Plaintiff Siemens Medical Solutions USA, Inc.'s motion for preliminary injunction should be denied in all respects.

Kelly E. Farnan

Jesse A. Finkelstein (#1090)
Finkelstein@rlf.com
Jeffrey L. Moyer (#3309)
Moyer@rlf.com
Kelly E. Farnan (#4395)
Farnan@rlf.com
Richards, Layton & Finger, P.A.
One Rodney Square, P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
Attorneys for Defendant/ Counterclaim-Plaintiff Saint-Gobain Ceramics & Plastics, Inc.

OF COUNSEL:

Frederick L. Whitmer
John C. Ohman
Thelen Reid Brown Raysman & Steiner LLP
875 Third Avenue
New York, NY 10022
(212) 603-2000

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on November 1, 2007, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF which will send notification of such filing to the following and which has also been served as noted:

BY ELECTRONIC MAIL AND HAND DELIVERY

Jack B. Blumenfeld
Maryellen Noreika
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
Wilmington, DE 19899

I hereby certify that on November 1, 2007, the foregoing document was sent to the following non-registered participants in the manner indicted:

BY ELECTRONIC MAIL AND FEDERAL EXPRESS

Gregg F. LoCascio
Charanjit Brahma
Sean M. McEldowney
Kirkland & Ellis LLP
655 15th Street, N.W.
Washington, DC 20005-5793

Kelly E. Farnan (#4395)